



Billing Code: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
[60Day-13-0010]

Proposed Data Collections Submitted for
Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Leroy Richardson, at 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Birth Defects Study To Evaluate Pregnancy exposures (BD-STEPS) (formerly titled The National Birth Defects Prevention Study (NBDPS)), (OMB 0920-0010, Expiration 04/30/2015) - Revision - National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC has been monitoring the occurrence of serious birth defects and genetic diseases in Atlanta since 1967 through the Metropolitan Atlanta Congenital Defects Program (MACDP). The MACDP is a population-based surveillance system for birth defects currently covering three counties in Metropolitan Atlanta.

Since 1997, CDC has funded case-control studies of major birth defects that utilize existing birth defect surveillance registries (including MACDP) to identify cases and study birth defects causes in participating states/municipalities across the United States.

BD-STEPS is a case-control study that is similar to the previous CDC-funded birth defects case-control study, NBDPS, which stopped interviewing participants in 2013. As with NBDPS, control infants will be randomly selected from birth certificates or birth hospital

records; mothers of case and control infants will be interviewed using a computer-assisted telephone interview.

The BD-STEPS interview takes approximately forty-five minutes to complete. A maximum of 275 interviews are planned per year per center, 200 cases and 75 controls. With seven centers planned, the maximum interview burden for all centers combined would be approximately 1,444 hours. As with NBDPS, parents in BD-STEPS will be asked to collect deoxyribonucleic acid (DNA) samples from themselves and their infants. The collection of saliva cells by the mother, father and infant takes about 15 minutes per person. For the infant sample, the parent will rub long-handled sponges between the infant's cheek and gum; parents will be asked to swab a total of 5 sponges per infant. The infant's mother and father will be asked to provide their own saliva samples by spitting into a funnel connected to small collection tubes. Collection of the saliva samples takes approximately 2-5 minutes per person, but the estimate of burden is 15 minutes per person to account for reading and understanding the consent form and specimen collection instructions and mailing back the completed kits. The anticipated maximum burden for collection of the saliva samples for all centers combined would be approximately 1,444 hours.

Information gathered from both the interviews and the DNA specimens has been and will continue to be used to study independent genetic and environmental factors as well as gene-environment interactions for a broad range of carefully classified birth defects.

This request is submitted to obtain OMB clearance for three additional years.

There are no costs to the respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of responses per respondent	Avg. burden per response (In hours)	Total Burden Hours
Mothers (interview)	Telephone consent and BD-STEPS questionnaire	1,925	1	45/60	1,444
Mothers, fathers, infants (saliva samples)	Written consent for saliva collection and collection of saliva samples	5,775	1	15/60	1,444
TOTAL					2,888

Leroy A. Richardson
Chief, Information Collection Review Office
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention